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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,389	12/05/2003	Kevin Smith	SYN-8312	9231

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EXAMINER	
WOO, JULIAN W	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,389	SMITH ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-89* is/are pending in the application.

4a) Of the above claim(s) *67-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-66 and 83-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker (2,108,206) in view of Heil, Jr. et al. (5,514,174), and further in view of Ley (5,514,076). Meeker discloses the invention substantially as claimed. Meeker discloses, at least in the figures and in col. 1, line 51 to col. 2, line 41; a retractor including a rigid body (1); a retraction device for manipulating or grasping an object, where the device has a head (2, 3, or distal portion of 1) connected to the distal end of the body; two, flexible needles (4a or 4b) of resilient metal; and a removable actuation device (9) connected to the proximal end of the body; where the body

has a longitudinal extent, where the head is connected removably or integrally formed (i.e., integrated) with the body; where the head has two head halves (i.e., the head is symmetrical with respect to a longitudinal axis and can be defined by two halves formed together) and defines tracks (5a), which have track exits (5); where the tracks exits open in a direction at a substantially orthogonal angle to the longitudinal direction, where the track exits are disposed to permit movement therethrough substantially without friction and are disposed on opposing sides of the head, where the surfaces of the tracks guide the needles in a direction substantially orthogonal to a movement direction of the actuation device (see fig. 4), where the tracks have a shape corresponding to a memory shape of a portion of the needles, where the needles include a substantially linear proximal portion and an arcuate distal portion, where the arcuate shape of the portion is no greater than a circle and greater than a semi-circle (around 4c), where the material of the needles is a pseudo-elastic metal, where the actuation device has a rod (4) removably connected to or is integrally formed with (i.e., integrated with) the needles, where the retractor includes proximal stop (6), where the actuation device has a locking device (12) or an overstroke preventor, where the actuation device is a one-handed actuation device, where the head has an anchoring spike (2), where the actuation device selectively moves an actuator (8), where the needles are sized to control penetration depth into tissues, and where the needles are fixedly connected to the actuation device. However, Meeker does not disclose that the tracks are curved, where each track has an arcuate segment. Heil, Jr. et al. teach, at least in figure 5 and col. 8, lines 45-49; a

device with a needle (131) guided through a curved track (139) with arcuate segments (141, 143). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Heil, Jr. et al., to modify the tracks of Meeker's device, so that each is curved and has an arcuate segment. Such a track would allow a needle to be extended out of the head through movement of the actuation device, while allowing smooth, slidable movement of the needle from the head.

However, neither Meeker nor Meeker in view of Heil, Jr. et al. discloses flexible needles that are of a shape memory material having a memory shape. Ley teaches, at least in figure 2 and in col. 1, line 509 to col. 2, line 25 and col. 4, line 3 to col. 5, line 19; a retractor needle formed of a shape memory material (e.g., nitinol) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ley, to form the needles in the device of Meeker or Meeker in view of Heil, Jr. et al. out of a shape memory material having a memory shape. Such a material would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient.

Additionally, Meeker or Meeker in view of Heil, Jr. et al. and Ley does not disclose that the two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate

halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

3. Claims 1, 5, 11, 15, 17, 19, 26, 37, 39, 88, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittkampf (4,142,530) in view of Ley (5,514,076). Wittkampf discloses the invention substantially as claimed. Wittkampf discloses, at least in the figures and in col. 3, lines 14-32 and col. 4, lines 48-51; a retractor including a flexible body with a coil winding (37) and an outer jacket (31); a retraction device for manipulating or grasping an object, where the device has a head (30) connected to the distal end of the body; flexible needles (40, 38) of a resilient material; and an actuation device (44) connected to the proximal end of the body, where the needles include a portion of arcuate shape, where the head includes a set of curved tracks (within 35), where each track has an arcuate segment and track exits each having a diameter at least as large as a needle diameter, where the head includes a shim (52), where a segment of the arcuate-shaped portion of a needle remains in a track while the needles are extended out of and retracted into the head, and where the arcuate-shaped portion corresponds to a shape of an arcuate segment. However, Wittkampf does not disclose the flexible needles are of a shape memory material having a memory shape. Ley teaches, at least in figures 2 and 3 and in col. 1, line 59 to col. 2, line 25 and col. 4, line 3 to col. 5, line 19; needles formed of a shape memory material (e.g., nitinol) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ley, to form the needles in the device of Wittkampf out of a

shape memory material having a memory shape. Such a material is biocompatible and would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that any inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient. Wittkampf also does not disclose that the body and retraction device are sized to fit within the working channel of an endoscope. Nevertheless, it would have been a matter of obvious design choice to size the components of Wittkampf's device as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being with the level of ordinary skill in the art. Additionally, Wittkampf does not disclose that the two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

4. Claims 39 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggs et al. (6,599,311) in view of Heil, Jr. et al. (5,514,174). Biggs et al. disclose the invention substantially as claimed. Biggs et al. disclose, at least in figures 8-10 and 24A-24B and in col. 3, lines 44-46; col. 11, lines 21-53; col. 16, lines 39-50; and col. 17, lines 52-66; a combination of a flexible endoscope (e.g., 34) having at least one working channel and a tissue retractor (e.g., 200) including a flexible body (e.g., 35), a retraction device including a

head (e.g., 208), tracks (209) defined by the head, flexible needles (e.g., 204) of a shape memory material (e.g., nickel-titanium alloys) and including a portion with an arcuate shape; and an actuation device (e.g., 202) connected to a proximal end of the body, where upon actuation, the connector is moved to selectively extend the needles out of the head (see fig. 24B) and withdraw the needles into the head (see fig. 24A). However, Biggs et al. do not disclose that the head includes a set of curved tracks, where each track has a respective arcuate segment. Heil, Jr. et al. teach, at least in figure 5 and col. 8, lines 45-49; a device with a needle (131) guided through a curved track (139) with arcuate segments (141, 143). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Heil, Jr. et al., to modify the tracks of the device of Biggs et al., so that each is curved and has an arcuate segment. Such a track would allow a needle to be extended out of the head through movement of the actuation device, while allowing smooth, slidable movement of the needle from the head. Biggs et al. also do not disclose that the body and retraction device are sized to fit within the working channel of an endoscope. Nevertheless, it would have been a matter of obvious design choice to size the components of the device of Biggs et al. as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being with the level of ordinary skill in the art.

5. Claims 39-54, 58, 59, 61-65, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker (2,108,206) in view of Heil, Jr. et al. (5,514,174) and Ley (5,514,076), and further in view of Green (5,928,137). Meeker in view of Ley discloses substantially as claimed a tissue retractor including a rigid body and retraction device. However, Meeker in view of Ley does not disclose that the retractor is combined with a flexible endoscope having at least one working channel for receiving the body and the retraction device. Green teaches, at least in figures 1 and 5 and in col. 6, lines 49-65; a flexible endoscope having at least one working channel (e.g., 152) for receiving an endoscopic tool. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Green, to include a flexible endoscope with the device of Meeker in view of Heil, Jr. and Ley. A flexible endoscope with at least one working channel would not only allow access for the device of Meeker in view of Heil, Jr. and Ley to a surgical site, it would also allow diagnosis and imaging of the site, especially where the site has narrow, even tortuous confines.

Response to Amendment

6. Applicant's arguments filed on July 30, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding the rejection based on Meeker; Heil, Jr.; and Ley: Heil, Jr. indeed teaches a "radial opening" that is a "curved track" as claimed. "Track" has been given its broadest reasonable interpretation. That is, according to the ENCARTA World English

Dictionary, a definition of “track” includes “path: path or road," and the radial opening of Heil, Jr.’s device provides a path for passage of needle. The path also includes curved surfaces (at 141 and 143), so the opening can be defined as a “curved track.” Applicant’s argument that such curved surfaces provide “end stops” for the needle does not deny that the opening provides a path for needle movement, even pivoting needle movement; where Meeker (not Heil, Jr.) discloses sliding movement of a needle through a radial opening.

Applicant also contends that the Examiner did not provide a rationale for combining Heil, Jr. and Ley with Meeker, under 35 U.S.C. 103, to arrive at the claimed invention and that the Examiner applied hindsight reasoning. On the contrary and as shown in the rejection above, the Examiner indeed provide reasons for combining the references. First of all, the three references disclose surgical devices with needles for tissue engagement. Meeker and Heil, Jr. disclose devices with openings for needle passage, while Heil, Jr. provides a teaching regarding a "curved track" for a needle. As stated in the rejection, the motivation for modifying Meeker's device with Heil, Jr.’s teaching is: “Such a [curved] track would allow a needle to be extended out of the head through movement of the actuation device, while allowing smooth, slidable movement of the needle from the head.” Furthermore, Ley was brought into the reference combination simply for Ley’s teaching regarding the material for the needle. As stated above, the motivation for combining Ley with Meeker and Heil, Jr. is: “Such a [shape memory] material would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable

release force, so that inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient."

Regarding arguments regarding the rejection based on Wittkampf and Ley: Applicant argues that Wittkampf does not disclose a "curved track." As pointed out in the rejection, and as best seen in the cross-section of the device in figure 2, Wittkampf indeed shows a curved track through element 35 through which a needle passes. Ley was then brought into the rejection for Ley's teaching regarding the material for a needle.

Regarding the Applicant's argument that the Examiner's conclusions of obviousness are based upon improper hindsight reasoning: It must be recognized that any judgment on obviousness is in a sense necessarily based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. *In re Mclaughlin*, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). As shown in the rejections above, the Examiner gleaned knowledge from Meeker; Heil, Jr., and Ley or Wittkampf and Ley.

Regarding arguments regarding the rejection based upon Biggs and Heil Jr.: The Examiner agrees with the Applicant that Biggs does not disclose curved tracks for passage of needles. As shown in the rejection above, Heil, Jr. teaches a curved track for needle passage, and again, the Examiner provides a motivation for combining Heil, Jr. with Biggs under 35 U.S.C. 103: "Such a

[curved] track would allow a needle to be extended out of the head through movement of the actuation device, while allowing smooth, slidable movement of the needle from the head."

Regarding arguments regarding the rejection based on Meeker; Heil, Jr.; Ley and Green: The Applicant again contends that no "rational underpinning" was provided for the combination of references. On the contrary, the Examiner brought Green into the previously discussed combination of Meeker; Heil, Jr.; and Ley solely for Green's teaching of an endoscope combined with other surgical tools. The motivation for the combination is: "A flexible endoscope with at least one working channel would not only allow access for the device of Meeker in view of Heil, Jr. and Ley to a surgical site, it would also allow diagnosis and imaging of the site, especially where the site has narrow, even tortuous confines."

In short and in contrast to Applicant's contentions, the Examiner did not simply provide "single, half-sentence" clauses or "mere conclusory statements" to support the obviousness rejections. Indeed, the Examiner provided rational underpinning, i.e., motivations, for the abovementioned combinations of references.

The rejection under 35 U.S.C. 112 is hereby withdrawn.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

November 19, 2008